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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,863	08/14/2001	Megan K. Levings	DX01135	8706

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DNAX RESEARCH INSTITUTE
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EXAMINER

ANDRES, JANET L.

ART UNIT PAPER NUMBER

1646

DATE MAILED 03/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/929,863

Applicant(s)

LEVINGS ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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RESPONSE TO AMENDMENT

1. Applicant's amendment filed 12 December 2002 is acknowledged. Claims 1-7 and 10-14 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections/Objections Withdrawn

2. The objection to the specification is withdrawn in response to Applicant's amendment.
3. The rejection of claims 15-18 under 35 U.S.C. 102(b) is withdrawn in response to Applicant's cancellation of these claims.
4. The rejection of claim 16 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained/New Grounds of Rejection

5. The rejection of claims 1-7 and 11-14 under 35 U.S.C. 112, first paragraph, as they pertain to *in vitro* methods is maintained for reasons of record in the office action of paper no. 7, because the specification, while being enabling for methods *in vivo* and using cord blood T cells, does not reasonably provide enablement for differentiation in the absence of IL-10 *in vitro*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Applicant argues that Lin teaches effects in very early stage cells while the amended claims encompass only naïve CD4⁺ cells. This argument is found persuasive and this basis of the rejection is withdrawn.

Applicant further argues that only IFN- α is needed for, for example, cord blood T cells. However, as stated in the previous office action, Applicant teaches on p. 10, line 23, that both

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IFN- α and IL-10 are necessary for differentiation. It is clear from the teachings on p. 9 that cord blood T cells are able to provide the IL-10; however, the claims are not limited to cord blood T cells. While one of skill in the art would predictably be able to differentiate cells in circumstances in which IL-10 is present, such as *in vivo* or using cord blood T cells or when it is added exogenously, one of skill in the art would not be able to induce such differentiation in the absence of IL-10, according to Applicant's own teachings on pp. 7-10.

Applicant additionally argues that antigen and IL-15 are shown in the specification to cause proliferation of naïve CD4⁺ cells and Tr1 cells, respectively. This argument is found persuasive and this basis of the rejection is withdrawn.

6. Claims 1-7, 10, and 13 are newly rejected under 35 U.S.C. 102(b) as being anticipated by WO 88/03411 (Cummins, 1988).

On consideration, these claims encompass effects *in vivo*. Since IL-10 would be expected to be present *in vivo*, any time IFN- α was administered to a patient, it would inherently have the claimed effect on naïve CD4⁺ cells, regardless of whether it was realized at the time. Cummins teaches oral administration of IFN- α to treat disease, including chronic inflammatory conditions, on p. 8, lines 13-29, and p. 27, lines 1-29, and p. 28, lines 1-29. Such treatment would result in the differentiation of naïve CD4⁺ cells, as claimed in claim 1. Claims 2-7 indicate that characteristics of the cells produced; they do not alter the method itself from what is claimed in claim 1. As stated above; IL-10 would be expected to be present *in vivo* and thus the limitations of claim 10 would inherently be met. Similarly, IL-15 would inherently cause proliferation when it was present, meeting the limitations of claim 13. Thus, regardless of

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whether the consequences discovered by Applicant were recognized at the time, the claimed methods are anticipated by the methods of treatment set forth in WO 88/03411.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7 and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. patent 6,346,243, Brod, 2002. Brod teaches administration of IFN- α to suppress transplant rejection: see column 6, lines 53-67, column 7, lines 1-3, figures 2 and 3. The transplants express alloantigens; the alloantigens were thus administered with the IFN- α . As stated above, the results observed by Applicant would inherently have occurred and Brod thus anticipates Applicant's claimed invention of co-administration of IFN- α and alloantigen.

While claim 14 lacks enablement commensurate in scope with the claims, it is not anticipated by or obvious over WO 88/03411 or the '243 patent, because neither document teaches or provides motivation for testing of TR1 cells for antigen specificity.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[yvonne.eyler@uspto.gov\]](mailto:lyvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
Patent Examiner

March 12, 2003